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**UNITED STATES DISTRICT COURT
DISTRICT OF UTAH**

SOLOMON ABADY, Individually and on
behalf of all others similarly situated,

Plaintiff,

v.

LIPOCINE INC. and MAHESH V. PATEL,

Defendants.

**AMENDED CLASS ACTION COMPLAINT
FOR VIOLATIONS OF THE FEDERAL
SECURITIES LAWS**

JURY TRIAL DEMANDED

CLASS ACTION

Civil No. 2:19-cv-00906-CW-CMR

District Judge Clark Waddoups
Magistrate Judge Cecilia M. Romero

Lead Plaintiff Sergus Thomas and Named Plaintiff Thomas Parkinson (collectively, “Plaintiffs”), individually and on behalf of all other persons similarly situated, by Plaintiffs’ undersigned attorneys, for Plaintiffs’ complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiffs and Plaintiffs’ own acts, and information and belief as to all other matters, based upon, inter alia, the investigation conducted by and through Plaintiffs’ attorneys, which included, among other things, a review of the defendants’ public documents, and announcements made by defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Lipocine, Inc. (“Lipocine” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants who purchased the publicly traded securities of Lipocine from January 28, 2019 through November 11, 2019, both dates inclusive (the “Class Period”). Plaintiffs seek to recover compensable damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder.

2. Lipocine is a specialty pharmaceutical company that primarily focuses on the development of oral delivery of pharmaceutical products in the area of men’s and women’s health. Lipocine’s lead product candidate is TLANDO (LPCN 1021), an oral testosterone replacement therapy. The Company had previously submitted New Drug Applications (“NDA”) for TLANDO

twice and, both times, received Complete Response Letters (“CRL”)¹ from the U.S. Food and Drug Administration (“FDA”) rejecting the NDAs. The Company received the first CRL in June 2016 and the second in May 2018.

3. Lipocine has never generated revenue from product sales. The Company had accumulated over \$138 million in deficit by the end of 2018 and had a net loss of \$11.7 million in 2018. In its 2018 Form 10-K, the Company disclosed that it “will need substantial additional capital in the future,” and “[i]f additional capital is not available, we will have to delay, reduce or cease operations.” Pursuant to a 2018 loan agreement, the Company was required to maintain \$5 million in cash collateral with Silicon Valley Bank until TLANDO was approved by the FDA. In the first three months of 2019, the Company kept itself afloat by raising over \$6 million from the sale of nearly 3 million shares of its common stock.

4. Lipocine’s financial stresses reached a boiling point on March 27, 2019, when the FDA granted approval to Jatenzo, an oral testosterone competitor to TLANDO developed by Clarus Therapeutics. Faced with a crippling loss of investment income from the prospect of a rival drug beating TLANDO to market, the Company announced that same day that it would resubmit the NDA for TLANDO in the second quarter of 2019. On April 2, in an attempt to delay the commercial release of Jatenzo, Lipocine sued Clarus in federal court in Delaware alleging that Jatenzo violated six of Lipocine’s patents.

5. On May 8, 2019, the Company filed its Form 10-Q for the first quarter of 2019. The 2019 Q1 10-Q described Lipocine’s July 2018 Post-Action Meeting with the FDA, where they discussed the ways in which Lipocine could cure the four deficiencies identified by the FDA in

¹ A Complete Response Letter is a communication from the FDA to a company stating that an application cannot be approved in its present form.

the May 2018 CRL. Lipocine told investors that the FDA “provided specific feedback on potential resolution of each deficiency, including clinical design elements where appropriate.” Lipocine added that “the data analyses we are performing together with the results from the definitive phlebotomy study and the ABPM clinical study should address the deficiencies identified by the FDA in its CRL.”

6. According to the Company, one of the four deficiencies identified in the May 2018 CRL for TLANDO was “verifying the reliability of Cmax data and providing justification for non-applicability of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO.” Cmax is a measure of maximal serum testosterone concentrations. The pre-determined Cmax limits for the secondary endpoints are:

- Testosterone Cmax ≤ 1500 ng/dL in at least 85% of subjects;
- Testosterone Cmax between 1800 and 2500 ng/dL in not more than 5% of subjects;
- and
- Testosterone Cmax > 2500 ng/dL in no subject.

7. Rather than conducting a new clinical trial, Lipocine announced in its 2019 Q1 10-Q that it was “performing additional analyses of existing data in order to address the Cmax deficiency.” Lipocine’s existing data came from a 2017 study (the “DV Study”) that formed the basis of Lipocine’s second failed NDA for TLANDO in August 2017.

8. Critically, throughout the Class Period, the Company portrayed the Cmax results from the DV study as barely missing the required secondary endpoints: “*In the DV study SS Cmax per dose analysis, the percentage of subjects with Cmax less than 1500 ng/dL and between 1800 ng/dL and 2500 ng/dL were 85% and 7%, respectively.*” Deviations from the predetermined limits in the DV study were observed in the Cmax per day dose analysis for these thresholds. Only one

subject, who was a major protocol violator, exceeded the 2500 ng/dL limit independent of per dose or per day dose analyses.”

9. The purported near-miss of the secondary endpoints in the DV study created optimism among investors and analysts because Jatenzo had just been approved despite also barely missing the required secondary endpoints. One analyst provided a chart to show that TLANDO’s Cmax characteristics were comparable to those of the recently approved Jatenzo:

Exhibit I – Comparison of Registrational Study Outcomes for Oral Testosterone³

FDA Cmax Threshold	Study Outcome	
	Jatenzo	Tlando DV
Min 85% < 1500 ng/dL	83%	85%
<= 5% 1800-2500 ng/dL	3%	7%
0% > 2500 ng/dL	3%	~1%*

*1 subject of 94 was >2500 ng/dL and a major protocol violator

10. Defendants encouraged the comparison to Jatenzo. At a September 24 Ladenburg Healthcare Conference, CEO Mahesh Patel stated that the Company was “*hopeful of approval in light of seeing that FDA has recently approved two products . . . earlier this year.*” When asked about the Company’s interactions with the FDA in the past month, Patel stated that “[t]here have been some information requests, but I would say nothing too concerning. We had four deficiencies that were identified in the last CRL. We think we were able to answer all four of them, adequately.”

11. Throughout the Class Period, Defendants repeatedly expressed optimism about TLANDO approval and the \$2 billion market for the product.

12. The truth finally emerged on November 11, 2019, when Lipocine issued a press release announcing that it had received yet another CRL from the FDA regarding its NDA for TLANDO. The sole deficiency identified in the CRL was the failure of the efficacy trial to meet the three secondary endpoints for Cmax.

13. Unbeknownst to investors, Lipocine had repeatedly misled investors about the Cmax secondary endpoints in the DV Study by emphasizing the *per dose* analysis rather than the *per day dose* analysis.

14. The DV Study measured Cmax in two ways:

- The first, which the Company refers to as “**per day dose**” in its public filings with the SEC, measures Cmax as the maximum serum concentration of testosterone that occurred in the 24-hour period following the morning dose of TLANDO. Under this measure, there is one observation for each of the 95 subjects in the DV Study. This measure forms the basis of the predetermined secondary endpoints for Cmax required by the FDA as applied to TLANDO, Jatenzo, and all comparable drug candidates.
- The second, which the Company refers to as “**per dose**” in its public filings with the SEC, measures Cmax as the maximum serum concentration of testosterone that occurred in the 12-hour periods following both the morning and evening doses of TLANDO. Under this measure, there are two observations for each of the 95 subjects—or a total of 190 observations. This measure was not the basis of the predetermined secondary endpoints for Cmax required by the FDA.

15. Defendants were well aware that the FDA was evaluating the secondary endpoints based on the *per day* (0-24h) analysis. Rather than meeting one secondary endpoint and barely missing the other two—like the previously approved Jatenzo—the “per day” analysis of the DV Study showed that TLANDO badly missed all three secondary endpoints:

Testosterone Cmax Outliers 225 mg Twice Daily Trial



Testosterone Cmax Outliers	FDA Target	Tlando
Cmax ≤1500 ng/dL	≥85%	74%
Cmax >1800-2500 ng/dL	≤5%	14%
Cmax >2500 ng/dL	No subjects	One subject

16. None of Defendants’ public statements during the Class Period disclosed the *per day* Cmax results. Instead, Defendants falsely told investors that TLANDO’s secondary endpoints for Cmax were “*generally consistent with approved products.*” In fact, the TLANDO secondary endpoints for Cmax were significantly worse than those of any comparable approved product. Reactions from analysts demonstrated that Defendants’ had successfully misled the market.

17. On this news, Lipocine’s stock price fell \$1.93 per share, or 70.7%, to close at \$0.80 per share on November 11, 2019. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s securities, Plaintiffs and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

18. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

19. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

20. Venue is proper in this judicial district pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as Defendants conduct business and the Company is headquartered in this District.

21. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

22. Lead Plaintiff Sergus Thomas, as set forth in the previously filed Certification incorporated herein by reference, purchased the Company's securities at artificially inflated prices during the Class Period and was damaged upon the revelations of the alleged corrective disclosures.

23. Named Plaintiff Thomas Parkinson purchased the Company's securities at artificially inflated prices during the Class Period and was damaged upon the revelations of the alleged corrective disclosures.²

² Mr. Parkinson's Certification is attached as Exhibit 1 hereto.

24. Defendant Lipocine is a Delaware corporation with its principal executive offices located at 675 Arapeen Drive, Suite 202, Salt Lake City, Utah 84108. The Company's securities trade in an efficient market on the NASDAQ Stock Market ("NASDAQ") under the ticker symbol "LPCN."

25. Defendant Mahesh V. Patel ("Patel") has served as President, CEO, and Director of Lipocine since co-founding the Company in 1997 and served as Chairman at all relevant times. He holds a PhD in Pharmaceuticals and an MS in Physical Pharmacy. According to the Company's proxy statements, Patel's dual role as an executive officer and director gives him unique insights into the day-to-day operations of the Company and its strategic planning and clinical development.

26. Defendant Patel:

- a. directly participated in the management of the Company;
- b. was directly involved in the day-to-day operations of the Company at the highest levels;
- c. was privy to confidential proprietary information concerning the Company and its business and operations;
- d. was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;
- e. was directly or indirectly involved in the oversight or implementation of the Company's internal controls;
- f. was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or
- g. approved or ratified these statements in violation of the federal securities laws.

27. The Company is liable for the acts of Patel and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

28. The scienter of Patel and other employees and agents of the Company is similarly imputed to the Company under *respondeat superior* and agency principles.

29. The Company and Patel are referred to herein, collectively, as the “Defendants.”

SUBSTANTIVE ALLEGATIONS

I. Background

30. Headquartered in Salt Lake City, Utah, Lipocine is a specialty pharmaceutical company that focuses on the development of pharmaceutical products in the area of men’s and women’s health. The Company’s primary development programs are based on oral delivery solutions for poorly bioavailable drugs.

31. Lipocine’s lead product candidate is TLANDO (LPCN 1021), an oral testosterone replacement therapy. TLANDO is the only product candidate for which the Company has submitted an NDA to the FDA. Lipocine incurred over \$4 million of external research and development costs in 2018, over 85% of which were for TLANDO. In the first quarter of 2019, the Company spent over \$1.3 million on external research and development for TLANDO, which accounted for over 94% of the Company’s external research and development expenses.

32. As of December 31, 2018, the Company had only 10 full time employees—only five of whom were engaged in drug development activities.

33. TLANDO is an oral capsule containing testosterone undecanoate (TU) in a lipid formulation. TU is a straight chain fatty acid ester of testosterone that is not alkylated at the 17-alpha position. TLANDO is designed to enable absorption of TU via the intestinal lymphatic

pathway. TU is converted to testosterone by non-specific esterases present in the body. TLANDO is a product candidate for testosterone replacement therapy (“TRT”) in adult males for conditions associated with a deficiency or absence of endogenous testosterone (“hypogonadism”)

Lipocine Submits First NDA For TLANDO

34. Before the Company can market TLANDO in the United States, it has to obtain FDA approval of the drug and apparatus under a §505(b)(2) NDA.

35. The FDA requires rigorous scientific testing to ensure that a drug is safe and effective for its intended use before the FDA will permit it to be marketed in the United States. Before considering approval of a drug for its indicated use, the FDA requires a “sponsor” to submit a NDA for consideration, which contains data from clinical trials, preclinical studies, and manufacturing information that supports the product’s safety and efficacy. 21 U.S.C. 355(b); 21 CFR 314.50(d).

36. Lipocine submitted the original NDA for TLANDO on August 31, 2015. The 2015 NDA was based on the Company’s Phase 3 clinical Study of Oral Androgen Replacement (“SOAR” or “Study 13-001”), which evaluated the efficacy and safety of TLANDO. In SOAR, subjects were initially started at 225 mg testosterone undecanoate (TU) twice daily, which is equivalent to approximately 142 mg of testosterone twice daily. If needed, the dose was titrated up to 300 mg TU twice daily or down to 150 mg TU twice daily, and was dependent on serum testosterone levels measured during week 3 and week 7. “Titration” is the process of gradually adjusting the dose of a medication until optimal results are reached.

37. On June 29, 2016, the Company disclosed that it had received a CRL from the FDA regarding the 2015 TLANDO NDA. The CRL was based on the fact that the dosing regimen used in SOAR “differed significantly” from the dosing regimen proposed in the 2015 NDA.

III. Lipocine Conducts The DV Study For Second TLANDO NDA

38. In response to the 2016 CRL, the Company met with the FDA in a Post Action Meeting. The FDA informed Lipocine that the Company's new proposed dosing regimen would need validation in a clinical trial prior to any resubmission of the TLANDO NDA.

39. The Company conducted two studies in response to the FDA's request: the Dosing Validation Study ("DV Study" or "Study 16-002") and the Dosing Flexibility Study ("DF Study" or "Study 16-003").

40. The DV and DF studies were both an open-label, fixed dose (no titration), single treatment clinical study of oral TRT in hypogonadal males with low testosterone that assessed TLANDO in hypogonadal males on a fixed daily dose of 450 mg. The daily 450 mg dose was divided into two equal doses in the DV study and into three equal doses in the DF study. In total, 95 and 100 subjects were enrolled into DV and DF studies, respectively, with 94 and 98 subjects completing the DV and DF studies, respectively.

41. The FDA requires that efficacy trials for testosterone replacement products meet both primary and secondary endpoints.

42. The primary efficacy endpoint for the DV and DF Studies was the percentage of Tlando-treated subjects who achieved a 24-hour average serum testosterone concentration within the normal range (i.e., 300-1080 ng/dL) upon completion of 24 days of treatment. For this endpoint to be met, the minimum acceptable percentage was 75% with a lower bound of the associated 95% confidence interval being 65% or more.

43. Trials for testosterone therapies also have standard secondary endpoints to assess for unacceptably high maximal exposures to testosterone that could raise safety concerns. The secondary endpoint for the DV and DF Studies was defined as the percentage of subjects who

exhibited serum total testosterone Cmax within the predetermined limits upon completion of approximately 24 days of treatment. These secondary endpoints assess the percentage of subjects with testosterone Cmax ≤ 1500 ng/dL (target is at least 85%), the percentage of subjects with testosterone Cmax between 1800 and 2500 ng/dL (target is $\leq 5\%$), and the percentage of subjects with testosterone Cmax > 2500 ng/dL (target is no subject).

44. On June 19, 2017, the Company announced the results of the DV and DF Studies. Based on these results, Patel announced that the Company would resubmit the TLANDO NDA in the third quarter of 2017. In August 2017, Lipocine resubmitted the TLANDO NDA to the FDA based on the results of the DV Study.

45. On January 10, 2018, the FDA's Center for Drug Evaluation and Research held a Bone, Reproductive, and Urologic Drugs Advisory Committee (the "BRUDAC Meeting") Meeting to discuss the pending TLANDO NDA.

46. Both Lipocine³ and the FDA⁴ prepared briefing materials for the Brudac Meeting. At the meeting, five people presented on behalf of Lipocine. Lipocine's presenters included Patel and Anthony DelConte, MD, who served as Lipocine's Chief Medical Director. Importantly, while there were certain disagreements between Lipocine and the committee, both parties agreed that (i) the secondary endpoints for both the DV and DF Studies were based on Cmax measured *per day* ("**0-24h**"); and (ii) the DV Study did not meet any of the three secondary endpoints.

³ <https://www.fda.gov/media/110373/download>

⁴ <https://www.fda.gov/media/110350/download>

47. Lipocine's presentations at the BRUDAC Meeting included a slide acknowledging that C_{max}(0-24h) was the proper measure for secondary endpoints and that the DV Study did not meet any of the secondary endpoints:

Study 16-002: Secondary Endpoints (T C_{max})

T C _{max} Criteria	Target % Subjects	T C _{max} (0-24h) N=95
<1500 ng/dL	≥85%	74%
1800–2500 ng/dL	≤5%	14%
>2500 ng/dL	0%	1% ^a

^a One subject had C_{max} value of 2730 ng/dL (one single measurement >2500 ng/dL).

48. The FDA's presentation⁶ for the BRUDAC Meeting also stated that C_{max}(0-24h) was the proper measure for secondary endpoints and that the DV Study did not meet any of the secondary endpoints:



Testosterone C_{max} Outliers

- During Study 2, the secondary efficacy endpoint was not met for any of the predetermined limits.

Measure	Target	T C _{max} (0-24h)
C _{max} (0-24h) < 1500 ng/dL, %	≥ 85%	74%
1800 ≤ C _{max} (0-24h) ≤ 2500 ng/dL, %	≤ 5%	14%
C _{max} (0-24h) > 2500 ng/dL (n)	No subject	One subject

- Subject with T C_{max}(0-24h) > 2500 ng/dL had a history of cholecystectomy, which was one of the exclusion criteria. It is unclear whether this protocol violation contributed to the C_{max} excursion.

⁵ <https://www.fda.gov/media/110672/download>

⁶ <https://www.fda.gov/media/110654/download>

49. Hylton Joffe, the director of the Division of Bone, Reproductive, and Urologic Products in CDER at the FDA, described the above slide at the BRUDAC Meeting:

This slide shows the outliers for testosterone Cmax or peak testosterone concentrations, and these are three standard secondary endpoints for testosterone replacement therapy that attempt to assess for unacceptably high testosterone concentrations. In each row, I've shown each of the three criteria. The middle column shows what FDA's target is for each of those criteria, and then the last column shows the Tlando results.

As you can see, Tlando did not meet any of these three standard secondary endpoint criteria. For example, for the Cmax less than or equal to 1500 nanograms per deciliter, FDA's target is that at least 85 percent of subjects should meet that criteria. For Tlando, it was 74 percent.

In the next one, which is Cmax between 1800 and 2500 nanograms per deciliter, FDA's prespecified target is that it should be in that range no more than 5 percent of subjects. For Tlando, it was 14 percent. Then for Cmax greater than 2500, no subjects should meet that, and there was one subject with Tlando, so we'll have the committee explore this issue in detail over the course of the day.

50. Similarly, the FDA briefing document for the BRUDAC Meeting stated:

The secondary efficacy endpoint for [the DV and DF Studies] was defined as the percentage of subjects who exhibited serum total T Cmax(0-24h) within the predetermined limits upon completion of approximately 24 days of treatment. These predetermined testosterone limits were:

1. Cmax(0-24h) \leq 1500 ng/dL in \geq 85% of subjects
2. Cmax(0-24h) between 1800 and 2500 ng/dL in \leq 5% of subjects
3. Cmax(0-24h) $>$ 2500 ng/dL in no subjects

In LPCN 1021-16-002 (the study dosing 225 mg twice daily), Tlando met the primary efficacy endpoint, but none of the predetermined limits of the secondary endpoint.

51. Notably, *none of the briefing documents, presentations, or speakers from either the FDA or Lipocine even mentioned—much less discussed as a relevant criterion—the DV study SS Cmax “per dose” analysis that Defendants repeatedly highlighted to investors.*

52. The day before the BRUDAC Meeting, BRUDAC held a meeting with Clarus concerning the Jatenzo NDA. The Jatenzo NDA also proposed a twice daily dosage, with subjects in the Jatenzo efficacy study receiving a morning dose and an evening dose. When discussing the secondary endpoints, the briefing documents and presentations from both Clarus and the FDA focused entirely on the Cmax per day (0-24h) measurement.

53. At the end of the TLANDO BRUDAC Meeting, the Committee members overwhelmingly concluded that the overall risk/benefit profile of TLANDO was unacceptable to support approval as a testosterone replacement therapy. In part due to Tlando's failure to meet the secondary efficacy endpoints for Cmax, thirteen of the nineteen Committee members voted that the benefit/risk profile of Tlando was unacceptable.

54. On May 8, 2018, the Company received a second CRL from the FDA regarding the TLANDO NDA. According to the Company, the CRL identified four deficiencies in the TLANDO NDA:

The CRL identified four deficiencies which include the following: determining the extent, if any, of *ex vivo* conversion of testosterone undecanoate ("TU") to testosterone ("T") in serum blood collection tubes to confirm the reliability of T data; obtaining definitive evidence pre-approval via an ambulatory blood pressure monitoring study as to whether TLANDO causes a clinically meaningful increase in blood pressure in hypogonadal men; ***verifying the reliability of Cmax data and providing justification for non-applicability of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO***; and, determining the appropriate stopping criteria that can reproducibly and accurately identify those patients who should discontinue use of TLANDO. The CRL also identified additional comments that are not considered approvability issues.

Defendants Mislead Investors In Desperate Attempt To Raise Capital

55. Desperate for cash, the Company took out a \$10 million loan from Silicon Valley Bank on January 5, 2018—just five days before the BRUDAC Meeting. The principal borrowed under the loan bears interest at a rate equal to the Prime Rate plus one percent per annum, which

interest is payable monthly. The loan matures on December 1, 2021. Under the terms of the loan, following the May 2018 CRL, Lipocine is required to maintain \$5 million of cash collateral at SVB until such time as TLANDO is approved by the FDA. The loan matures on December 1, 2021.

56. Throughout 2018, the Company was only required to make monthly interest payments. Beginning on January 1, 2019, the Company was required to also make equal monthly payments of principal and interest for the remainder of the term. The principal payments that began in 2019 require the Company to repay \$3.33 million of principal each year until the loan matures. The Company is also required to pay an additional final payment at maturity equal to \$650,000.

57. In January 2019, bleeding cash and lacking income, Lipocine turned to selling shares of the Company's common stock to finance its operations. In order to generate interest in its stock, the Company decided to prematurely push a resubmission of the TLANDO NDA despite not having resolved the issues identified in the 2018 CRL. After raising just \$700,000 in proceeds from the sales of its common stock in all of 2018, the Company raised \$6.2 million through sales of its common stock in just the first three months of 2019.

58. Following a July 2018 Post Action Meeting with the FDA to discuss a process for addressing the deficiencies raised in the 2018 CRL, the Company conducted an ABPM clinical study to resolve the FDA's blood pressure concerns and conducted a phlebotomy study to resolve the FDA's concern about the reliability of T data.

59. In contrast to the direct action the Company took to address the other deficiencies identified in the 2018 CRL, the Company had not yet addressed TLANDO's Cmax-related deficiency. Rather than taking the required time, effort, and expenses to attempt to address the

Cmax deficiencies, Defendants instead chose to mislead investors in the Company's rush to secure enough cash to continue operating.

60. Defendants' desperation to raise capital was also apparent in the timing of its March 27, 2019 announcement that it would resubmit the TLANDO NDA. This announcement came the same day that the FDA granted approval to the Jatenzo NDA, a rival oral testosterone product. Less than a week later, on April 2, 2019, Lipocine sued the company that makes Jatenzo alleging that it infringed on six of Lipocine's patents, in a desperate attempt to delay Jatenzo from beating TLANDO to market.

61. Throughout the Class Period, Defendants intentionally created a false impression that the Cmax secondary endpoints were not a significant impediment to the FDA's approval of TLANDO.

62. Defendants repeatedly misled investors into believing that the "per dose" Cmax analysis of the DV Study was more important than the "per day" Cmax (0-24h) analysis:

- Each of the Company's quarterly and annual filings during the Class Period touted the "per dose" Cmax analysis before mentioning the "per day" analysis.
- Each of the Company's quarterly and annual filings during the Class Period touted the "per dose" findings that "the percentage of subjects with Cmax less than 1500 ng/dL and between 1800 ng/dL and 2500 ng/dL were 85% and 7%, respectively" which was generally consistent with the 85% and 5% FDA secondary endpoint requirements. In contrast, the Company never disclosed the "per day" findings that the percentage of subjects with Cmax less than 1500 ng/dL and between 1800 ng/dL and 2500 ng/dL were 74% and 14%, respectively. Instead, Defendants intentionally hid these poor results by merely stating that "[d]eviations from the predetermined limits in the DV study were observed in the Cmax per day dose analysis for these thresholds."

- The Company never disclosed that the discussion of secondary endpoints at the BRUDAC Meeting focused exclusively on the “per day” Cmax results or that neither the Company nor the Committee even mentioned the “per dose” findings that Defendants repeatedly touted to investors.
- The Company never disclosed that the failure of the “per day” analysis to meet the secondary endpoints could be, alone, sufficient for another CRL.
- The Company told investors in a corporate presentation that “secondary endpoints [were] generally consistent with approved products.” While the “per dose” findings were arguably consistent with some other approved products, the “per day” findings were significantly worse than any other approved product. This slide reinforced the false and misleading impression that the “per dose” analysis was crucial—if not determinative—for resolution of the Cmax deficiency.

63. Defendants misled investors about the significance of the “per dose” analysis because the “per dose” Cmax findings were closer to those of other approved testosterone products. Significantly, other testosterone products have been approved despite slight deviations from the secondary endpoints established by the FDA.

64. The FDA has never approved an oral or gel testosterone product that significantly deviated from the FDA’s secondary endpoints for Cmax:

Table 10: Comparison of Total T C_{max} Profile of JATENZO to Other Approved T gel Products

Product	C _{max} < 1500 ng/dL N (%)	1800 ng/dL < C _{max} ≤ 2,500 ng/dL N (%)	C _{max} > 2,500 ng/dL N (%)	Average C _{avg} (ng/dL)	Average C _{max} (ng/dL)
JATENZO ^a (Day 105)	125/151 (82.8)	5/151 (3.3)	4/151 (2.6)	403	1008
Androgel 1.62% (Day 112)	159/179 (88.8)	10/179 (5.6)	2/179 (1.1)	561	845
Testim (Day 90)	191/199 (96.0)	4/199 (2)	0/199 (0)	612	897
Axiron (Day 120)	128/135 (94.8)	4/135 (3)	1/135 (0.7)	480	792
Fortesta (Day 90)	122/129 (94.6)	2/129 (1.5)	0/129 (0)	440	528
Natesto (Day 90)	58/69 (84.1)	1/69 (1.5)	0/69 (0)	421	1044

^a As JATENZO T concentrations were measured in plasma using NaF/EDTA tubes, the following adjusted T C_{max} ranges were used:

C_{max} ≤ 1,361 ng/dL; C_{max} > 1,633-2,268 ng/dL; C_{max} > 2268 ng/dL

65. As demonstrated by the above table—which was compiled by the FDA in connection with its approval of the Jatenzo NDA—no comparable product has been approved with less than 82.8% of subjects with C_{max} less than 1500 ng/dL or with more than 5.6% of subjects with C_{max} between 1800 ng/dL and 2500 ng/dL. TLANDO missed these marks substantially when evaluated by the proper “per day” analysis, which is why Defendants intentionally withheld this crucial information from investors. By misleading investors about the importance of the “per dose” analysis, Defendants were misleading investors about the likely success of the TLANDO NDA being approved by the FDA.

66. Defendants’ success in misleading investors about the significance of the “per dose” C_{max} analysis is evidenced by analysts’ reactions to the November 2019 CRL.

67. A November 2019 analyst report from Zacks Small Cap Research relied on the Company's "per dose" analysis to argue that TLANDO had barely deviated from the secondary endpoints: "FDA guidelines call for 85% of subjects to achieve a Cmax below 1500 ng/dL and no more than 5% of subjects presenting a Cmax between 1800 ng/dL and 2500 ng/dL and 0% above 2500 ng/dL. *In the most recent dosing validation (DV) study, 85% of subjects were below 1500 ng/dL and 7% were between 1800 ng/dL and 2500 ng/dL.*" Further, the analyst stated it was "likely that Lipocine will pursue a formal dispute resolution process with the FDA and make the case that Cmax characteristics for Tlando are consistent with" those of the recently-approved Jatenzo. The analyst then posted a table he had created, citing the FDA Label for Clarus' Jatenzo and a Lipocine quarterly SEC filing as his data sources:

FDA Cmax Threshold	Study Outcome	
	Jatenzo	Tlando DV
Min 85% < 1500 ng/dL	83%	85%
<= 5% 1800-2500 ng/dL	3%	7%
0% > 2500 ng/dL	3%	~1%*

*1 subject of 94 was >2500 ng/dL and a major protocol violator

68. This table further demonstrates that Defendants successfully misled the analyst. The data cited for Jatenzo is from the "per day" Cmax analysis, despite the fact that Jatenzo's efficacy study used the same twice-daily dosing that the DV Study used. The Zachs SCR analyst,

just like investors, was intentionally misled by Defendants into comparing the “per dose” analysis of TLANDO with the “per day” analysis of Jatenzo.⁷

69. An analyst from Ladenburg Thalmann & Co. Inc. was similarly misled by Defendants regarding the importance of the “per dose” Cmax analysis. Relying on Defendants’ misleading statements, the Ladenburg analyst argued that Lipocine had reasonable ground to appeal the CRL given that the Jatenzo’s Cmax excursions were more even worse than TLANDO’s: “In our view, given the approval of the Clarus oral testosterone with Cmax excursions which were more profound than the TLANDO data, we believe LPCN has reasonable grounds to appeal the FDA’s decision as the two products should be evaluated using consistent Cmax criteria.” In fact, TLANDO’s Cmax results were far worse than Jatenzo’s Cmax results under the “per day” analysis that formed the basis of the predetermined secondary endpoints for Cmax.

70. Defendants also misled investors about TLANDO’s failure to meet the third secondary endpoint, which is that no subjects have a Cmax above 2500 ng/dL. Defendants falsely stated that TLANDO had met this secondary endpoint, despite the fact that one of the subjects in the DV Study exceeded a Cmax of 2500 ng/dL. Defendants also misled investors by attempting to dismiss this subject by stating that he was a “was a major protocol violator” and not eligible for the DV Study. Defendants failed to disclose that the FDA’s BRUDAC Meeting briefing materials had rejected this argument because it was “unclear whether this protocol violation contributed to the Cmax excursion.”

⁷ In connection with its approval of the Jatenzo NDA, the FDA concluded that “3 out of 4 subjects that had a total T Cmax of > 2,500 ng/dL shows that the high concentrations are likely spurious and due to specimen contamination.”




Materially False and Misleading Statements

71. On January 28, 2019, the Company filed a Form 8-K with the SEC updating its corporate presentation that it uses when meeting with investors, analysts, and others. Patel signed the Form 8-K. The corporate presentation included a slide titled “TLANDO: Path Forward for Resubmission Confirmed” that described the Company’s “Deficiencies and Plan for Resolution.” The slide stated, in relevant part, that the Company’s resolution for its Cmax secondary endpoint deficiency was “[a]dditional analyses of existing data for resubmission.”

72. The January 28, 2019 corporate presentation also included a slide subtitled “Profile Demonstrated Clinically with Target Label Regimen.” Under a column labeled “Efficacy,” the slide falsely stated that TLANDO has “[m]et key secondary endpoint” and had “[o]ther secondary endpoints generally consistent with approved products.”

TLANDO™: Potential First Oral Option

Profile Demonstrated Clinically with Target Label Regimen

 Efficacy	 Safety	 Clear Benefits
<ul style="list-style-type: none"> ▪ Met primary endpoint <ul style="list-style-type: none"> - 80% response rate in “worst-case analysis” vs. FDA requirement of 75% ▪ Met key secondary endpoint <ul style="list-style-type: none"> - No eligible subjects with T levels >2500 ng/dL ▪ Other secondary endpoints generally consistent with approved products 	<ul style="list-style-type: none"> ▪ 591 subject exposure ▪ Well tolerated in 52 week exposure <ul style="list-style-type: none"> - AE profile comparable to active control, including GI - No cardiac, hepatic or drug related SAEs - No increase in mean BP with cuff measurements ▪ No apparent correlation of the observed Cmax excursions <ul style="list-style-type: none"> - ADRs, AEs, Meaningful changes in critical lab parameters 	<ul style="list-style-type: none"> ▪ Preferred oral option <ul style="list-style-type: none"> - No risk of accidental T transference - Non-invasive - Less cumbersome - Less burdensome - Simpler to prescribe - Fewer doctor visits - Easier for patients to properly use

73. The statements referenced in ¶¶ 71-72 above were materially false and/or misleading because they misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA, and which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the pre-determined secondary endpoints for Cmax were based on the “per day” analysis, not the “per dose” analysis; (2) only 74% of subjects were below Cmax 1500 ng/dL compared to the >85% target, and 14% of subjects were between Cmax 1800 and 2500 ng/dL compared to the <5% target; (3) the FDA had never approved a comparable testosterone product that deviated so significantly from the predetermined secondary endpoints; (4) the FDA had already concluded that it was unclear whether the protocol violation contributed to the Cmax excursion for the subject who exceeded the 2500 ng/dL limit; (5) consequently, the FDA was exceedingly unlikely to approve the TLANDO NDA given that the Company had failed to address the concerns surround the failure to meet the secondary endpoints; and (6) due to the foregoing, Defendants’ public statements were materially false and/or misleading at all relevant times.

74. On March 6, 2019, the Company filed a Form 10-K with the SEC, which provided its financial results and position for the fiscal year ended December 31, 2018 (the “2018 10-K”). Patel signed the 2018 10-K. In the 2018 10-K, the Company announced that it expected to resubmit the TLANDO NDA in mid-2019.

75. The 2018 10-K gave the false impression that the Company had resolved the Cmax deficiency identified in the 2018 CRL. The 2018 10-K stated, in relevant part:

The CRL identified four deficiencies which include the following: determining the extent, if any, of ex vivo conversion of TU to T in serum blood collection tubes to confirm the reliability of T data; obtaining definitive evidence pre-approval via an

ABPM study as to whether TLANDO causes a clinically meaningful increase in blood pressure in hypogonadal men, which is a surrogate marker of predicting cardiovascular outcomes; verifying the reliability of Cmax data and providing justification for non-applicability of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO; and, determining the appropriate stopping criteria that can reproducibly and accurately identify those patients who should discontinue use of TLANDO. . . .

On July 19, 2018, we completed a Post Action Meeting with the FDA in which the deficiencies raised in the CRL were discussed and a path forward for NDA resubmission for the potential approval of TLANDO was clarified. The FDA provided specific feedback on potential resolution of each deficiency, including clinical design elements where appropriate. . . . Finally, we are performing additional analyses of existing data in order to address the Cmax deficiency and dose stopping criteria deficiency identified by the FDA. Although there is no guarantee that TLANDO will ever be approved by the FDA, *we believe the data analyses we are performing together with the results from the definitive phlebotomy study and the on-going ABPM clinical study should address the deficiencies identified by the FDA in its CRL. Assuming results from the APBM clinical study support resubmission of the TLANDO NDA, we expect resubmission to occur mid-2019 followed by a six-month review by the FDA upon FDA acceptance.* There can be no assurances as to the timing or acceptance of our NDA by the FDA.

76. The 2018 10-K also described the secondary endpoints of the DV Study, giving a false impression that the DV Study had met two of the three secondary endpoints and had barely missed on the third. The 2018 10-K stated, in relevant part:

The secondary endpoints assessed the maximum total testosterone concentration (“Cmax”) post dosing using predetermined limits developed by the FDA for transdermals. The FDA guidelines for secondary efficacy success is that at least 85% of the subjects achieve Cmax less than 1500 ng/dL; no greater than 5% of the subjects have Cmax between 1800 ng/dl and 2500 ng/dL; and zero percent of the subjects have Cmax greater than 2500 ng/dL. Consistent with the definition of Cmax and the pharmacokinetic profile of multiple times a day dosing, two pre-specified analyses were performed, Cmax per dose and Cmax per day.

In the DV study SS Cmax per dose analysis, the percentage of subjects with Cmax less than 1500 ng/dL and between 1800 ng/dL and 2500 ng/dL were 85% and 7%, respectively. Deviations from the predetermined limits in the DV study were observed in the Cmax per day dose analysis for these thresholds. Only one subject, who was a major protocol violator, exceeded the 2500 ng/dL limit independent of per dose or per day dose analyses.

The DF study SS met all Cmax thresholds in per dose and per day dose analyses.

77. The statements referenced in ¶¶ 74-76 above were materially false and/or misleading because they misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA, and which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the pre-determined secondary endpoints for Cmax were based on the “per day” analysis, not the “per dose” analysis; (2) only 74% of subjects were below Cmax 1500 ng/dL compared to the >85% target, and 14% of subjects were between Cmax 1800 and 2500 ng/dL compared to the <5% target; (3) the FDA had never approved a comparable testosterone product that deviated so significantly from the predetermined secondary endpoints; (4) the FDA had already concluded that it was unclear whether the protocol violation contributed to the Cmax excursion for the subject who exceeded the 2500 ng/dL limit; (5) the DF Study meeting the secondary endpoints for Cmax was irrelevant to the FDA’s consideration of the TLANDO NDA; (6) consequently, the FDA was exceedingly unlikely to approve the TLANDO NDA given that the Company had failed to address the failure to meet the secondary endpoints; and (7) due to the foregoing, Defendants’ public statements were materially false and/or misleading at all relevant times.

78. On March 27, 2019, the Company issued a press release, which it filed with a Form 8-K with the SEC, announcing the results of the ABPM Study. Patel signed the Form 8-K. The press release included a quotation from Patel describing the ABPM study as a success and confirming that the Company would resubmit the TLANDO NDA in the second quarter of 2019:

“We are pleased with the TLANDO pressor results which we believe are in line with a recently approved testosterone replacement therapy. We look forward to resubmitting our NDA in the second quarter of 2019,” said Dr. Mahesh Patel,

Chairman, President and Chief Executive Officer of Lipocine. Dr. Patel further stated, “We remain committed on bringing our patient-friendly oral testosterone product candidate to patients in timely manner.”

79. The statements referenced in ¶ 78 above were materially false and/or misleading because they misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA, and which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the pre-determined secondary endpoints for Cmax were based on the “per day” analysis, not the “per dose” analysis; (2) only 74% of subjects were below Cmax 1500 ng/dL compared to the >85% target, and 14% of subjects were between Cmax 1800 and 2500 ng/dL compared to the <5% target; (3) the FDA had never approved a comparable testosterone product that deviated so significantly from the predetermined secondary endpoints; (4) the FDA had already concluded that it was unclear whether the protocol violation contributed to the Cmax excursion for the subject who exceeded the 2500 ng/dL limit; (5) the DF Study meeting the secondary endpoints for Cmax was irrelevant to the FDA’s consideration of the TLANDO NDA; (6) consequently, the FDA was exceedingly unlikely to approve the TLANDO NDA given that the Company had failed to address the failure to meet the secondary endpoints; and (7) due to the foregoing, Defendants’ public statements were materially false and/or misleading at all relevant times.

80. On May 1, 2019, the Company filed a Form 8-K with the SEC updating its corporate presentation that it uses when meeting with investors, analysts, and others. Patel signed the Form 8-K. The corporate presentation included a slide subtitled “Profile Demonstrated Clinically with Target Label Regimen.” Under a column labeled “Efficacy,” the slide gave a false

impression that the Company had clinically demonstrated a “[j]ustification for non-applicability of Cmax based missed secondary endpoints.”

81. The statements referenced in ¶ 80 above were materially false and/or misleading because they misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA, and which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the pre-determined secondary endpoints for Cmax were based on the “per day” analysis, not the “per dose” analysis; (2) only 74% of subjects were below Cmax 1500 ng/dL compared to the >85% target, and 14% of subjects were between Cmax 1800 and 2500 ng/dL compared to the <5% target; (3) the FDA had never approved a comparable testosterone product that deviated so significantly from the predetermined secondary endpoints; (4) the FDA had already concluded that it was unclear whether the protocol violation contributed to the Cmax excursion for the subject who exceeded the 2500 ng/dL limit; (5) the DF Study meeting the secondary endpoints for Cmax was irrelevant to the FDA’s consideration of the TLANDO NDA; (6) consequently, the FDA was exceedingly unlikely to approve the TLANDO NDA given that the Company had failed to address the failure to meet the secondary endpoints; and (7) due to the foregoing, Defendants’ public statements were materially false and/or misleading at all relevant times.

82. On May 8, 2019, the Company filed a Form 10-Q with the SEC, which provided its financial results and position for the fiscal quarter ended March 31, 2019 (the “2019 Q1 10-Q”). Patel signed the 2019 Q1 10-Q. In the 2018 10-K, the Company confirmed that it expected to resubmit the TLANDO NDA in May 2019.

83. The 2019 Q1 10-Q gave the false impression that the Company had resolved the Cmax deficiency identified in the 2018 CRL. The 2019 Q1 10-Q stated, in relevant part:

The CRL identified four deficiencies which include the following: determining the extent, if any, of ex vivo conversion of TU to T in serum blood collection tubes to confirm the reliability of T data; obtaining definitive evidence pre-approval via an ABPM study as to whether TLANDO causes a clinically meaningful increase in blood pressure in hypogonadal men, which is a surrogate marker of predicting cardiovascular outcomes; verifying the reliability of Cmax data and providing justification for non-applicability of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO; and, determining the appropriate stopping criteria that can reproducibly and accurately identify those patients who should discontinue use of TLANDO. . . .

On July 19, 2018, we completed a Post Action Meeting with the FDA in which the deficiencies raised in the CRL were discussed and a path forward for NDA resubmission for the potential approval of TLANDO was clarified. The FDA provided specific feedback on potential resolution of each deficiency, including clinical design elements where appropriate. . . . Finally, we are performing additional analyses of existing data in order to address the Cmax deficiency and dose stopping criteria deficiency identified by the FDA. ***Although there is no guarantee that TLANDO will ever be approved by the FDA, we believe the data analyses we are performing together with the results from the definitive phlebotomy study and the ABPM clinical study should address the deficiencies identified by the FDA in its CRL. We expect resubmission to occur in May 2019 followed by a six-month review by the FDA upon FDA acceptance.*** There can be no assurances as to the timing or acceptance of our NDA by the FDA.

84. The 2019 Q1 10-Q also described the secondary endpoints of the DV Study, giving a false impression that the DV Study had met two of the three secondary endpoints and had barely missed on the third. The 2019 Q1 10-Q stated, in relevant part:

The secondary endpoints assessed the maximum total testosterone concentration (“Cmax”) post dosing using predetermined limits developed by the FDA for transdermals. The FDA guidelines for secondary efficacy success is that at least 85% of the subjects achieve Cmax less than 1500 ng/dL; no greater than 5% of the subjects have Cmax between 1800 ng/dl and 2500 ng/dL; and zero percent of the subjects have Cmax greater than 2500 ng/dL. Consistent with the definition of Cmax and the pharmacokinetic profile of multiple times a day dosing, two pre-specified analyses were performed, Cmax per dose and Cmax per day.

In the DV study SS Cmax per dose analysis, the percentage of subjects with Cmax less than 1500 ng/dL and between 1800 ng/dL and 2500 ng/dL were 85% and 7%, respectively. Deviations from the predetermined limits in the DV study were observed in the Cmax per day dose analysis for these thresholds. Only one subject, who was a major protocol violator, exceeded the 2500 ng/dL limit independent of per dose or per day dose analyses.

The DF study SS met all Cmax thresholds in per dose and per day dose analyses.

85. On May 8, 2019, the Company issued a press release announcing its financial results and position for the fiscal quarter ended March 31, 2019. The press release included a quotation from Patel stating that “[w]ith the successful completion of the ABPM study for TLANDO, we look forward to resubmitting our NDA for TLANDO in May 2019.”

86. On May 14, 2019, the Company issued a press release, which it filed with a Form 8-K with the SEC, announcing that the FDA had accepted the TLANDO NDA and set November 9, 2019 as the Prescription Drug User Fee Act (“PDUFA”) goal date. Patel signed the Form 8-K. The press release gave a false impression that the Company had resolved its failure to meet the secondary endpoints for Cmax, stating in relevant part:

The NDA incorporates data compiled by Lipocine in order to address deficiencies identified by the FDA in a Complete Response Letter (“CRL”) to the Company in 2018 and discussed in the Post Action Meeting with the FDA.

87. The statements referenced in ¶¶ 82-86 above were materially false and/or misleading because they misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA, and which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the pre-determined secondary endpoints for Cmax were based on the “per day” analysis, not the “per dose” analysis; (2) only 74% of subjects were below Cmax 1500 ng/dL compared to the >85% target, and 14% of subjects were between Cmax

1800 and 2500 ng/dL compared to the <5% target; (3) the FDA had never approved a comparable testosterone product that deviated so significantly from the predetermined secondary endpoints; (4) the FDA had already concluded that it was unclear whether the protocol violation contributed to the Cmax excursion for the subject who exceeded the 2500 ng/dL limit; (5) the DF Study meeting the secondary endpoints for Cmax was irrelevant to the FDA's consideration of the TLANDO NDA; (6) consequently, the FDA was exceedingly unlikely to approve the TLANDO NDA given that the Company had failed to address the failure to meet the secondary endpoints; and (7) due to the foregoing, Defendants' public statements were materially false and/or misleading at all relevant times.

88. On August 7, 2019, the Company filed a Form 10-Q with the SEC, which provided its financial results and position for the fiscal quarter ended June 31, 2019 (the "2019 Q12 10-Q"). Patel signed the 2019 Q2 10-Q. In the 2018 10-K, the Company confirmed that it expected to resubmit the TLANDO NDA in May 2019.

89. The 2019 Q2 10-Q gave the false impression that the Company had resolved the Cmax deficiency identified in the 2018 CRL. The 2019 Q2 10-Q stated, in relevant part:

The CRL identified four deficiencies which include the following: determining the extent, if any, of ex vivo conversion of TU to T in serum blood collection tubes to confirm the reliability of T data; obtaining definitive evidence pre-approval via an ABPM study as to whether TLANDO causes a clinically meaningful increase in blood pressure in hypogonadal men, which is a surrogate marker of predicting cardiovascular outcomes; verifying the reliability of Cmax data and providing justification for non-applicability of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO; and, determining the appropriate stopping criteria that can reproducibly and accurately identify those patients who should discontinue use of TLANDO. . . .

On July 19, 2018, we completed a Post Action Meeting with the FDA in which the deficiencies raised in the CRL were discussed and a path forward for NDA resubmission for the potential approval of TLANDO was clarified. The FDA provided specific feedback on potential resolution of each deficiency, including

clinical design elements where appropriate. . . . Finally, we are performing additional analyses of existing data in order to address the Cmax deficiency and dose stopping criteria deficiency identified by the FDA. Although there is no guarantee that TLANDO will ever be approved by the FDA, ***we believe the data analyses we are performing together with the results from the definitive phlebotomy study and the ABPM clinical study should address the deficiencies identified by the FDA in its CRL.***

90. The 2019 Q2 10-Q also described the secondary endpoints of the DV Study, giving a false impression that the DV Study had met two of the three secondary endpoints and had barely missed on the third. 2019 Q2 10-Q stated, in relevant part:

The secondary endpoints assessed the maximum total testosterone concentration (“Cmax”) post dosing using predetermined limits developed by the FDA for transdermals. The FDA guidelines for secondary efficacy success is that at least 85% of the subjects achieve Cmax less than 1500 ng/dL; no greater than 5% of the subjects have Cmax between 1800 ng/dl and 2500 ng/dL; and zero percent of the subjects have Cmax greater than 2500 ng/dL. Consistent with the definition of Cmax and the pharmacokinetic profile of multiple times a day dosing, two pre-specified analyses were performed, Cmax per dose and Cmax per day.

In the DV study SS Cmax per dose analysis, the percentage of subjects with Cmax less than 1500 ng/dL and between 1800 ng/dL and 2500 ng/dL were 85% and 7%, respectively. Deviations from the predetermined limits in the DV study were observed in the Cmax per day dose analysis for these thresholds. Only one subject, who was a major protocol violator, exceeded the 2500 ng/dL limit independent of per dose or per day dose analyses.

The DF study SS met all Cmax thresholds in per dose and per day dose analyses.

91. The statements referenced in ¶¶ 88-90 above were materially false and/or misleading because they misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA, and which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the pre-determined secondary endpoints for Cmax were based on the “per day” analysis, not the “per dose” analysis; (2) only 74% of subjects were below Cmax 1500 ng/dL compared to the >85% target, and 14% of subjects were between Cmax

1800 and 2500 ng/dL compared to the <5% target; (3) the FDA had never approved a comparable testosterone product that deviated so significantly from the predetermined secondary endpoints; (4) the FDA had already concluded that it was unclear whether the protocol violation contributed to the Cmax excursion for the subject who exceeded the 2500 ng/dL limit; (5) the DF Study meeting the secondary endpoints for Cmax was irrelevant to the FDA's consideration of the TLANDO NDA; (6) consequently, the FDA was exceedingly unlikely to approve the TLANDO NDA given that the Company had failed to address the failure to meet the secondary endpoints; and (7) due to the foregoing, Defendants' public statements were materially false and/or misleading at all relevant times.

92. On September 24, 2019, Patel gave a presentation at the Ladenburg Thalmann Healthcare Conference. During a question and answer session with a Ladenburg analyst, Patel gave a false impression that the Company had resolved its failure to meet the Cmax secondary endpoints and that the FDA had not raised any concerns about the Company's failure to address this issue.

Matthew Kaplan, Analyst, Ladenburg Thalmann

Thanks. I think we have time maybe for a couple of questions. Just starting off, obviously, as you said that, you have PDUFA date middle of November – November 9. Can you give us a sense in terms of how your interaction has been with the FDA kind of going into the last month here, roughly, and what your sense is given, it seems as though you addressed the four issues that you had in the CRL previously and most outstanding the ambulatory blood pressure study, which was lacking.

Mahesh V. Patel, Chairman, President and Chief Executive Officer

Yes, I would characterize as a [inaudible] with FDA today. There's nothing abnormal. It's probably to be normal. There have been some information requests, but I would say nothing too concerning. We had four deficiencies that were identified in the last CRL. We think we were able to ask all four of them, adequately. Of course, we'll have to wait and see even the actual, the PDUFA date,

we got approval or not. Historically, we have had a couple of rounds and some surprises. So we're optimistically – I should say cautiously optimistic about – might hopeful of approval in light of seeing that FDA has recently approved two products some few injections as well as an oral product triclabendazole earlier this year.

93. The statements referenced in ¶ 92 above were materially false and/or misleading because they misrepresented and failed to disclose adverse facts pertaining to the likelihood of the FDA approving the 2019 TLANDO NDA, and which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the pre-determined secondary endpoints for Cmax were based on the “per day” analysis, not the “per dose” analysis; (2) only 74% of subjects were below Cmax 1500 ng/dL compared to the >85% target, and 14% of subjects were between Cmax 1800 and 2500 ng/dL compared to the <5% target; (3) the FDA had never approved a comparable testosterone product that deviated so significantly from the predetermined secondary endpoints; (4) the FDA had already concluded that it was unclear whether the protocol violation contributed to the Cmax excursion for the subject who exceeded the 2500 ng/dL limit; (5) the DF Study meeting the secondary endpoints for Cmax was irrelevant to the FDA’s consideration of the TLANDO NDA; (6) consequently, the FDA was exceedingly unlikely to approve the TLANDO NDA given that the Company had failed to address the failure to meet the secondary endpoints; and (7) due to the foregoing, Defendants’ public statements were materially false and/or misleading at all relevant times.

The Truth Emerges

94. On November 11, 2019, Lipocine issued a press release announcing receipt of a CRL from the FDA regarding its NDA for TLANDO. In that press release, Lipocine advised investors that the FDA had again rejected the NDA for TLANDO—this time because an efficacy

trial had not met three secondary endpoints for Cmax. Specifically, the press release stated, in relevant part

Lipocine . . . announced today that it has received a [CRL] from the [FDA] regarding its [NDA] for TLANDO™, the Company's oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form.

The CRL identified one deficiency stating the efficacy trial did not meet the three secondary endpoints for maximal testosterone concentrations ("Cmax"). The CRL does not identify any specific issues relating to the chemistry, manufacturing and controls ("CMC") of TLANDO.

"We are disappointed by the FDA's decision and intend to request a meeting with the FDA as soon as possible to discuss a potential path forward for the approval of TLANDO," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine.

95. On this news, Lipocine's stock price fell \$1.93 per share, or 70.7%, to close at \$0.80 per share on November 11, 2019. Lipocine's stock price continued tumbling to close at \$0.40 per share on November 14.

96. Defendants' false and misleading statements caused the precipitous decline in the market value of the Company's securities. As a result, Plaintiffs and other Class members have suffered significant losses and damages.

ADDITIONAL INFERENCES OF SCIENTER

97. As alleged herein, the Company and Patel acted with scienter because the Company and Patel knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as

primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Patel, by virtue of his receipt of information reflecting the true facts regarding Lipocine, his control over, and/or receipt and/or modification of Lipocine's materially misleading misstatements and/or their associations with the Company which made him privy to confidential proprietary information concerning Lipocine, participated in the fraudulent scheme alleged herein.

98. Patel knew or recklessly disregarded the false and misleading nature of the information that he caused to be disseminated to the investing public. The fraudulent scheme described herein could not have been perpetrated during the Class Period without the knowledge and complicity or, at least, the reckless disregard of the personnel at the highest levels of the Company, including Patel.

99. The following additional facts give rise to strong inference that Lipocine and Patel acted with scienter.

100. TLANDO was the Company's primary and most important product candidate, and success of the 2019 NDA was crucial to the Company's viability and success and was Defendants' key focus during the Class Period. The fraud alleged herein involves Lipocine's core operations, and the Company had only 5 employees working on drug development activities. Knowledge of the fraud may therefore be imputed to Patel.

101. Patel was intimately involved in the TLANDO development and approval process. He has made numerous detailed statements about TLANDO's safety and efficacy, the status of its trials, and the Company's interactions with the FDA. Patel presented on behalf of Lipocine at the BRUDAC Meeting, where secondary endpoints were thoroughly discussed and where Patel informed the Committee that he is the co-inventor of the technology that enabled Tlando.

102. Defendants were also well aware of their obligations not to mislead investors about its NDA. Defendants previously faced a securities fraud action in this Court in connection with misleading claims Defendants made about the first TLANDO NDA.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

103. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the publicly traded securities of Lipocine during the Class Period (the "Class"), and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

104. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

105. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

106. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

107. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- (a) whether Defendants' acts as alleged violated the federal securities laws;
- (b) whether Defendants' statements to the investing public during the Class Period misrepresented material facts about the financial condition, business, operations, and management of the Company;
- (c) whether Defendants' statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) whether Patel caused the Company to issue false and misleading SEC filings and public statements during the Class Period;
- (e) whether Defendants acted knowingly or recklessly in issuing false and misleading SEC filings and public statements during the Class Period;
- (f) whether the prices of the Company's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- (g) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

108. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

109. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (b) the omissions and misrepresentations were material;
- (c) the Company's securities are traded in efficient markets;
- (d) the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;
- (e) the Company traded on the NASDAQ, and was covered by multiple analysts;
- (f) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; Plaintiffs and members of the Class purchased and/or sold the Company's securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts; and
- (g) Unexpected material news about the Company was rapidly reflected in and incorporated into the Company's stock price during the Class Period.

110. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

111. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

**Violation of Section 10(b) of The Exchange Act and Rule 10b-5
Against All Defendants**

112. Plaintiffs repeat and realleges each and every allegation contained above as if fully set forth herein.

113. This Count is asserted against the Company and Patel and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

114. During the Class Period, the Company and Patel, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

115. The Company and Patel violated §10(b) of the 1934 Act and Rule 10b-5 in that they: employed devices, schemes and artifices to defraud; made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiffs and others similarly situated in connection with their purchases of the Company's securities during the Class Period.

116. The Company and Patel acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws.

These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

117. Patel had actual knowledge of the material omissions and/or the falsity of the material statements set forth above and intended to deceive Plaintiffs and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when he failed to ascertain and disclose the true facts in the statements made by them or other personnel of the Company to members of the investing public, including Plaintiffs and the Class.

118. As a result of the foregoing, the market price of the Company's securities was artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the Individual Defendants' statements, Plaintiffs and the other members of the Class relied on the statements described above and/or the integrity of the market price of the Company's securities during the Class Period in purchasing the Company's securities at prices that were artificially inflated as a result of the Company's and Patel's false and misleading statements.

119. Had Plaintiffs and the other members of the Class been aware that the market price of the Company's securities had been artificially and falsely inflated by the Company's and the Individual Defendants' misleading statements and by the material adverse information which the Company's and the Individual Defendants did not disclose, they would not have purchased the Company's securities at the artificially inflated prices that they did, or at all.

120. As a result of the wrongful conduct alleged herein, Plaintiffs and other members of the Class have suffered damages in an amount to be established at trial.

121. By reason of the foregoing, the Company and Patel have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiffs and the other members of the Class for substantial damages which they suffered in connection with their purchases of the Company's securities during the Class Period.

COUNT II

Violation of Section 20(a) of The Exchange Act Against Defendant Patel

122. Plaintiffs repeat and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

123. During the Class Period, Patel participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of his senior positions, he knew the adverse non-public information regarding the Company's business practices.

124. As an officer and director of a publicly owned company, Patel had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

125. Because of his position of control and authority as a senior officer, Patel was able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period. Throughout the Class Period, the Patel exercised his power and authority to cause the Company to engage in the wrongful acts complained of herein. Patel therefore, was a "controlling person" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, he participated in the unlawful conduct alleged which artificially inflated the market price of the Company's securities.

126. Patel, therefore, acted as a controlling person of the Company. By reason of his senior management position and being a director of the Company, Patel had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Patel exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

127. By reason of the above conduct, Patel is liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representatives;
- B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
- D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

DATED this 26th day of May, 2020.

Respectfully submitted,

/s/ Mitchell A. Stephens

Mitchell A. Stephens

JAMES DODGE RUSSELL & STEPHENS, P.C.

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